

# **EXHIBIT 26**

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June 30, 2017

Via Email (Alan.Slobodin@mail.house.gov) & U.S. Mail

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Chief Counsel for Oversight and Investigations  
United States House of Representatives,  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20515-6115

Re: May 8, 2017 Letter to Cardinal Health

Dear Alan:

On behalf of Cardinal Health, we are writing in response to the Committee's letter of May 8, 2017, addressed to George Barrett. We are pleased to provide you with responses to your specific questions below, and look forward to a continuing dialogue with you.

Headquartered in Dublin, Ohio, Cardinal Health, Inc. is an integrated healthcare services company, delivering products and logistics support to healthcare providers worldwide. In its role as a wholesale pharmaceutical distributor, Cardinal Health provides a controlled distribution channel from manufacturers to pharmacies and other healthcare providers, delivering a broad assortment of medications prescribed by doctors for treatment of their patients.

Cardinal Health does not practice medicine, meet the patient, diagnose medical conditions or needs, or write prescriptions; only licensed healthcare providers do. In fact, federal and state privacy laws generally prohibit pharmacies and other healthcare providers from revealing to Cardinal Health who their patients are and what medications they receive. Cardinal Health also does not advertise, market, or otherwise promote the use of prescription opiates to patients or healthcare providers who prescribe medications. Cardinal Health only ships medications to pharmacies and healthcare providers appropriately licensed by the Drug Enforcement Administration (DEA) and state regulators—in the case of West Virginia, the

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state's Board of Pharmacy. The vast majority of Cardinal Health's pharmaceutical distribution business is not related to opioid medications.

Cardinal Health shares the Committee's view, as expressed in its letter, that all players in the health care community have a responsibility to help prevent opioid abuse and diversion and we are committed to doing our part to help ensure opioids are used appropriately. Our responsibility as a distributor is to ensure that prescribers and pharmacists have access to the medications they need when and where they need them to provide to patients, while also maintaining systems to prevent the diversion of opioids from our distribution channel. Specifically, DEA regulations require Cardinal Health to report to the DEA "suspicious orders" of controlled substances, which are defined as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."<sup>1</sup> To meet that responsibility, Cardinal Health operates a state-of-the-art, constantly adaptive, rigorous system to combat controlled substance diversion. We are glad to share with the Committee the following information about Cardinal Health's distribution and anti-diversion practices in response to the Committee's specific questions.

- 1. Please provide the number of pills of hydrocodone and oxycodone sold by Cardinal Health to purchasers in West Virginia each year from 2005 through 2016.*

Cardinal Health's distribution of oxycodone and hydrocodone to retail pharmacies in West Virginia for the years 2005 through 2016 is reflected in the following chart. As you will see from the additional information included in the chart, there are several points that provide a critical framework for understanding these numbers, which are explained in the text below the chart.

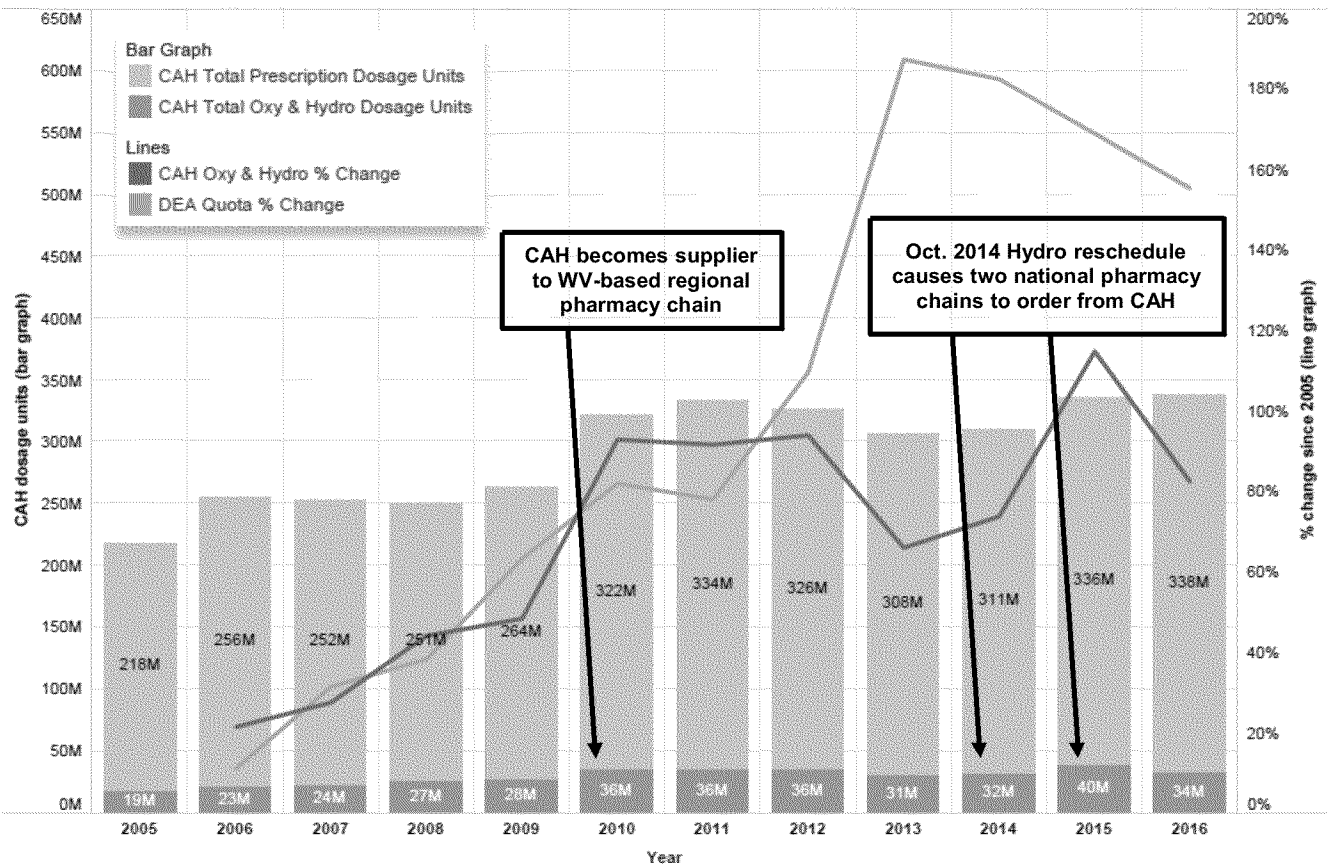
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<sup>1</sup> 21 C.F.R. § 1301.74(b).

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**CAH Distributions in West Virginia**

First, as you are aware, the DEA determines the volume of opioids allowed to be legally manufactured every year in the United States in order to meet legitimate medical need. Each year, DEA assigns annual quotas for manufacturers' production of Schedule I and II controlled substances, including opioids, based on its assessment of the quantity of such drugs needed for legitimate medical use in the United States. In 2004, the DEA released a report in which it reflected the then-prevailing professional judgment of the medical community that "chronic pain is a serious problem for many Americans. It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified."<sup>2</sup> Over the past two decades, the DEA generally increased its assessment of the amount of oxycodone and hydrocodone that is required to meet medical and research needs, consistent with widely accepted and publicized medical norms guiding physicians' prescribing

<sup>2</sup> DEA Interim Policy Statement on Dispensing Controlled Substances for the Treatment of Pain. 69 Fed. Reg. 67170 (Nov. 16, 2004).

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practices during that time period.<sup>3</sup> The percentage change in the DEA's annual quotas for oxycodone and hydrocodone from 2005 through 2016 is reflected in the yellow line in the chart above, with Cardinal Health's distribution percentage changes over the same time period shown by the green line.

Second, as reflected in the bar graph above, Cardinal Health's distributions of oxycodone and hydrocodone to West Virginia reflect only a small portion of the company's total distributions of prescription medications in the State. We do not believe the oxycodone and hydrocodone numbers can be meaningfully evaluated outside of the context of the total distribution numbers, which are shown in the gray bars.

Third, third-party reporting reflects that West Virginia, historically a state with higher levels of dangerous manual labor jobs, suffers from high rates of chronic injuries and diseases such as diabetes, hypertension, cancer, depression, and obesity<sup>4</sup> and is one of the most medicated states in the nation with respect to all prescription drugs.<sup>5</sup> Even so, Cardinal Health's distributions of oxycodone and hydrocodone to West Virginia pharmacies were never in amounts that exceeded what was reasonably calculated to be necessary for pharmacies to meet the legitimate medical needs of patients. Based on average prescription sizes, Cardinal Health's distributions to West Virginia pharmacies were sufficient to allow each pharmacy to fill between 4.5 and 6.5 prescriptions for oxycodone or hydrocodone per day.<sup>6</sup>

Fourth, in evaluating the oxycodone and hydrocodone distributions reflected in the purple bars in the chart, it is important to understand that increases in the numbers from year to year can be reflective of a change in the number and types of pharmacies and healthcare providers Cardinal Health served throughout and across each year. In addition, the ordering habits of pharmacies and other healthcare providers change over time, depending on numerous factors, including pricing and availability of particular medications. By way of example, the data in the

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<sup>3</sup> DEA Diversion Control Division, Aggregate Production Quota History for Selected Substances. Available online at: [https://www.deadiversion.usdoj.gov/quotas/quota\\_history.pdf](https://www.deadiversion.usdoj.gov/quotas/quota_history.pdf) DEA does not assign quotas or allowances to distributors. Rather, distributors supply to pharmacies and other health care providers the controlled substance medications that the DEA has permitted manufacturers to produce.

<sup>4</sup> See, e.g., West Virginia Dep't of Health & Human Resources, 2012 West Virginia State Health Profile, available at <http://www.dhhr.wv.gov/publichealthquality/statepublichealthassessment/Documents/2012%20State%20Health%20Profile%20Final%20May%202013.pdf> annual data reported by Trust for America's Health, available at <http://healthyamericans.org/states/?stateid=WV#section=1,year=2013,code=undefined>

<sup>5</sup> See, e.g., annual data reported by Kaiser Family Foundation, Retail Prescription Drugs Filled at Pharmacies (Annual Per Capita), available at <http://www.kff.org/health-costs/state-indicator/retail-rx-drugs-per-capita/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

<sup>6</sup> This calculation is based on an average of 60 pills per prescription, which is fewer pills than the national average based on calculations using DEA and available industry data. While acute pain prescriptions typically contain fewer pills, prescriptions for chronic pain patients are generally higher.

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chart above reflects two significant instances of how these types of changes affected Cardinal Health distributions:

- In October 2014, hydrocodone was moved from Schedule III to Schedule II of the Controlled Substances Act. Two major pharmacy chains that are Cardinal Health customers purchase direct from manufacturers and warehouse their own Schedule III-V controlled substances and non-controlled substances. The rescheduling of hydrocodone to Schedule II caused those large pharmacy chain customers to begin placing orders for hydrocodone from Cardinal Health, because their own facilities did not have the security features required to warehouse Schedule II substances (e.g., a locked vault within the warehouse, etc.). This shift caused an increase in the number of hydrocodone units shipped by Cardinal Health that is visible in the chart above. This increase was a shift in distribution, not a true increase in overall supply of hydrocodone to those chain pharmacy locations in West Virginia.
- In 2010, Cardinal Health became the wholesaler supplier for a regional chain pharmacy that is headquartered in West Virginia. The addition of this regional chain caused a substantial increase in the number of units of oxycodone and hydrocodone—as well as all other medications—shipped by Cardinal Health to West Virginia that is visible in the chart above. Again, the increase was a shift in distribution from another distributor to Cardinal Health, not a true increase in overall supply of hydrocodone and oxycodone to those pharmacies.

2. *Please provide the names and addresses of your distribution centers that served West Virginia each year from 2005 through 2016.*

Cardinal Health has a Distribution Center located in Wheeling, WV that serves pharmacies and other healthcare providers located in West Virginia (as well as other states). The address is 71 Mil Acres Drive, Wheeling, WV, 26003. Over 98% of all shipments of pharmaceutical products to pharmacies and other healthcare providers in West Virginia come from the Wheeling Distribution Center, which employs over 275 individuals. The Wheeling Distribution Center has been routinely inspected by the West Virginia Board of Pharmacy and the DEA and neither agency has alleged that the Wheeling Distribution Center made inappropriate distributions or failed to report suspicious orders of controlled substances.

3. *Does Cardinal Health have monitoring systems in place to detect unusual or suspicious patterns or quantities of opioid orders? If so, please describe those monitoring systems. Do your distribution centers that serve West Virginia have their own policies and systems for monitoring opioid orders, or do they follow or rely on your company's monitoring system?*



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Yes. Cardinal Health maintains a sophisticated, state-of-the-art anti-diversion program that includes advanced analytics, technology and on-the-ground deployment of investigators to evaluate pharmacies, identify aberrant ordering patterns, scrutinize customers and orders, and identify, block and report orders of prescription controlled substances medications that do not meet our strict anti-diversion criteria. Cardinal Health owns and operates all of its own distribution centers, so every distribution center is part of and subject to our anti-diversion program. Every customer is subject to our anti-diversion process for every order. Our anti-diversion program is as central to our business as our sales or logistical operations.

Cardinal Health's anti-diversion team of about 85 individuals examines data across all of the company's logistics and delivery operations. The team includes investigators, statistical auditors and data analysts, pharmacists, and compliance officers deployed on-site at our pharmaceutical distribution centers, in the field, and at our corporate headquarters. Cardinal Health's anti-diversion program consists of three main components: Know Your Customer, Electronic Monitoring, and Site Visits.

1. Know Your Customer. Know Your Customer is the process by which Cardinal Health learns about pharmacies to, among other things, better understand the range of legitimate requirements for controlled substances and establish distribution thresholds on a customer-specific basis. Cardinal Health uses a multi-factor process to evaluate pharmacies, even before they can be accepted as a Cardinal Health customer. These factors include the product mix dispensed by the pharmacy within certain drug families, the location and business model of the pharmacy, the historic volume of controlled substances dispensed, and the ratio of controlled to non-controlled substances. Cardinal Health uses an escalation process to evaluate higher volume customers which includes two-person approval for certain threshold levels and regular review of higher volume customers by a committee of anti-diversion management and specialists.
2. Electronic Monitoring. All Cardinal Health customers are subjected to electronic monitoring for every order, which occurs prior to order fulfillment. Threshold limits are established by the anti-diversion team for over 120 families of controlled substances, including oxycodone and hydrocodone, for each pharmacy or other healthcare provider. The thresholds are based on various factors specific to the customer and analysis of third-party data detailing dispensing volumes of pharmacies nationwide. Thresholds are based on 12 annual accrual cycles. Through electronic monitoring, Cardinal Health monitors dosage units for each controlled substance drug family, as well as certain strengths of specific drugs known to be more frequently misused (e.g., oxycodone 15mg and 30mg products). When a store's accrued orders hit the established threshold, the order is held and, outside of a rare occurrence, the order is cancelled. All cancelled orders are reported to the DEA and any required state regulators (in West Virginia, to the Board of Pharmacy).

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3. Site Visits. Cardinal Health conducts regular site visits to its customers across the country as part of its anti-diversion program. Site visits may be announced or unannounced. In 2016, Cardinal Health representatives conducted 20,000 on-site inspections nationwide. These representatives look for any visible signs of diversion, such as long lines, a high volume of customers from out-of-state, lack of product diversity in non-prescription products offered for sale, or groups of people traveling together to fill prescriptions. As warranted by the circumstances, the teams also speak with the Pharmacist-in-Charge and/or other staff and review aggregate pharmacy dispensing data to identify any risk of diversion. The data reviewed includes aggregate prescription volume, percentage of cash business, ratio of controlled to non-controlled substance dispensing, and information about the pharmacy's customer base (e.g., hospice, orthopedics, oncology, pain clinics, etc.). However, it is important to note that privacy laws, such as HIPAA and other laws, prohibit Cardinal Health representatives from the review of patient specific prescriptions.

Every distribution center, including the one located in Wheeling, West Virginia, has an on-site compliance officer and is subject to the company's anti-diversion policies and procedures. Distribution center employees are also required to bring to the attention of the anti-diversion team any order of controlled substances they believe to be suspicious, irrespective of whether the order also triggers Cardinal Health's electronic monitoring system.

4. *What policies and procedures does Cardinal Health and/or your distribution centers that serve West Virginia have in place to take action in response to those detections, including notification of DEA and other authorities? Did you company or your distribution centers that serve West Virginia provide investigative leads to law enforcement authorities?*

Cardinal Health maintains comprehensive tracking, monitoring and data reporting systems relating to controlled substances. We report all of our distributions of all oxycodone and hydrocodone to the DEA through DEA's ARCOS system on a monthly basis. In addition, Cardinal Health reports, to both the DEA and the West Virginia Board of Pharmacy, any orders placed by pharmacy customers in West Virginia that do not meet our strict criteria for fulfillment. It is important to note that the orders reported by Cardinal Health to regulators are not *necessarily* indicative of diversion. Orders reported as suspicious simply exceed the strict limits that we have established to control the volume of controlled substances a pharmacy customer can receive from Cardinal Health. Cardinal Health reports all such orders to DEA and to any state agency designated by state law because those agencies have visibility into the entire distribution chain, including access to or the ability to obtain important data Cardinal Health does not (and in some cases cannot) have such as patient and prescriber information. These



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reporting mechanisms ensure a free flow of relevant information to those agencies best equipped to interpret that data.

*5/6. Did Cardinal Health and/or your distribution centers that serve West Virginia identify any patterns of opioid distribution to West Virginia that caused you to make a referral to the State Board of Pharmacy, DEA, or other authorities? If so, when did you become aware of those patterns? Please describe what actions were taken after identifying such patterns, including a timeline for these actions.*

Our responsibility as a distributor is to monitor the orders placed by the more than 40,000 retail pharmacies and other healthcare providers we serve nationwide and to look for orders of unusual size, frequency, or those that substantially deviate from a normal ordering pattern. We fulfill that responsibility in all of the ways described above. As part of that process, every time we identify such an order, we decline to ship the product and report the order to regulators for their follow-up and action. If further information is requested from the DEA or state agencies, we cooperate and provide that information.

*7. If the reporting in the Gazette-Mail on opioid distribution to West Virginia is accurate, is Cardinal Health taking any specific action to examine its sales and monitoring processes in West Virginia and nationwide? If so, what actions have you taken to date and what additional actions are planned?*

Cardinal Health stands by the appropriateness of its distributions in West Virginia and the facts and figures laid out above in this letter, including the fact that, based on average prescription sizes, Cardinal Health's distributions to West Virginia pharmacies were sufficient to allow each pharmacy to fill between 4.5 and 6.5 prescriptions for oxycodone or hydrocodone per day. In addition to everything described above, utilizing our robust control processes and operationalized anti-diversion team, we continuously monitor and control our distributions of controlled substances. We also continuously monitor available information to learn about the methods and schemes of diverters and their ever-changing tactics. For example, buprenorphine is an opiate that is used to treat individuals who are addicted to other opiates. However, news outlets have reported that law enforcement has seen an increase in the diversion and abuse of buprenorphine, including trafficking of buprenorphine by criminal organizations in West Virginia. In response to that information, Cardinal Health has limited our distributions of a certain buprenorphine product. Our anti-diversion system is dynamic, allowing us to respond to emerging diversion schemes while remaining committed to our critical role in ensuring patients get the medications they need from their health care providers. Our anti-diversion program is continually evaluated for potential improvements, and is as central to our business as our sales or logistical operations.

Cardinal Health is also committed to opioid abuse education and community engagement nationwide. Cardinal Health works alongside regulators, professionals, our pharmacy customers

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and others in the healthcare supply chain (e.g., manufacturers, professional and trade associations) to collectively help educate pharmacies in identifying problematic patients and prescribers. For example, Cardinal Health was a leader in an effort with the National Association of Boards of Pharmacy (NABP) and other stakeholders (e.g., pharmacy and physician groups, manufacturers and distributors) to release a consensus document entitled “Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances,” available at <https://nabp.pharmacy/nabp-stakeholders-release-consensus-document-on-the-challenges-and-red-flag-warning-signs-related-to-prescribing-and-dispensing-controlled-substances/> and <https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf>. In addition, Cardinal Health worked closely with NABP and the Anti-Diversion Working Group to create the Red Flags Video which is being used to help educate pharmacists in identifying drug diversion arising from problematic patients or prescribers. This video can be found on the West Virginia Board of Pharmacy’s website at [http://www.wvbop.com/index.php?option=com\\_content&view=article&id=118%3Ared-flags&catid=1%3Alatest-news&Itemid=1](http://www.wvbop.com/index.php?option=com_content&view=article&id=118%3Ared-flags&catid=1%3Alatest-news&Itemid=1).

Generation Rx is a national prescription drug education and awareness program developed by the Cardinal Health Foundation and The Ohio State University College of Pharmacy in 2009. It raises awareness among people of all ages—from teens to student pharmacists to community leaders—about the dangers of misusing prescription medications. Cardinal Health employee ambassadors, students at Colleges of Pharmacy, and partner pharmacists use Generation Rx materials to present to schools and community groups and at key events. For more information on this program, see [www.CardinalHealth.com/community](http://www.CardinalHealth.com/community) or [www.GenerationRx.org](http://www.GenerationRx.org). The annual Generation Rx grant program supports non-profit organizations, schools of pharmacy, and others. Generation Rx’s 2016 grant program focused on drug disposal. Generation Rx’s 2017 grant program focuses on spreading best practices in pain management to reduce opioid prescriptions and encourage patient engagement.<sup>7</sup>

Cardinal Health partners with many in the fight against prescription drug misuse, including in the state of West Virginia. The Cardinal Health Foundation supports non-profit organizations with grant funding, used to raise awareness and knowledge about the dangers of prescription drug misuse and abuse. In West Virginia, the Cardinal Health Foundation has partnered with Community Anti-Drug Coalitions of America (CADCA) to connect with community substance abuse prevention coalitions on use of the Generation Rx teen education resources. Three coalitions are piloting the use of the materials in their community, including Weirton, WV-based coalition Advocates for Substance Abuse Prevention. From 2013 to 2015, Tyler’s Light Inc. received funding through this grant program which is being used to talk with high school students in the Wheeling area about the dangers of misusing controlled substance

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<sup>7</sup> GenerationRx 2017 Request for Proposal: Best Practices in Pain Medication Use and Patient Engagement. Available at: <http://www.cardinalhealth.com/content/dam/corp/web/documents/brochure/CARDINAL-HEALTH-Generation-Rx-Medication-Disposal-Grant-Program.pdf>.

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medications. In 2014, the Cardinal Health Foundation sponsored training in Wheeling, WV, titled “3D: A 3-Dimensional Approach to Prescription Drug Abuse Prevention.” The training discussed effective individual and environmental prevention strategies and creating solutions for how communities can work collaboratively on the issue.

Cardinal Health has also worked with many of its pharmacy customers in West Virginia to combat diversion. Cardinal Health customers Riesbeck’s Pharmacy and Elm Grove Pharmacy host medication take-back events in Wheeling and the surrounding communities each year. Cardinal Health supports the medication take-back events through event promotion and employees volunteering at the events. Cardinal Health and Kroger Pharmacy have worked together throughout the years on medication take-back events at the Wheeling Kroger Pharmacy. Cardinal Health customers Tri-State Pharmacy, Follansbee Pharmacy and Hoge-Davis Drug have led Generation Rx presentations in high schools throughout West Virginia. And Cardinal Health employees discuss Generation Rx with pharmacists each year at the annual West Virginia Pharmacists Association conference.

8. *Is there any data that DEA could share with your company, as appropriate given law enforcement and commercial confidential information sensitivities, that would help improve detection of suspicious orders of opioids?*

Cardinal Health believes that a collaborative and multi-faceted approach where all stakeholders—manufacturers, prescribers, pharmacists, distributors and regulators—work together will have the greatest impact on this problem. Wholesale distributors do not—and should not—engage in the day to day practice of pharmacy or medicine. We do not and cannot see specifics around prescription and patient information, and we do not interact with or see the patient. As a distributor, we have a responsibility to detect and report suspicious orders from our pharmacy and other healthcare provider customers based on the information available to us. As discussed previously, Cardinal Health maintains a sophisticated, state-of-the-art anti-diversion program to fulfill this obligation. If DEA provided information on emerging diversion trends observed by regulators, Cardinal Health would use that information in its anti-diversion program. It would also be helpful if DEA informed distributors when the DEA has a concern about any particular customer of that distributor. This information would allow distributors to provide heightened scrutiny of the customer’s orders while the DEA conducts its investigation.

. . .

Cardinal Health is committed to continuing our efforts in the fight against prescription drug misuse and abuse. We are grateful to have elected officials who share our concerns and are committed to addressing this issue, and we appreciate the opportunity to correspond with you about our efforts.

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Sincerely,

*/s/ Enu Mainigi*

Enu Mainigi